Ex 19 - ABDCMDL00269383-9387

Plaintiffs' Opposition to Defendants' Motion for Summary Judgment on Proximate Causation Grounds

U.S. Department of Justice
Drug Enforcement Administration

Office of the Deputy Administrator *Washington, D.C. 20537*

APR 19 2007

AmerisourceBergen Drug Corporation
2100 Directors Row
Orlando, Florida 32809

ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, 21 U.S.C. §§ 823 and 824,

NOTICE is hereby given to inform AmerisourceBergen Drug Corporation ("Respondent") of the immediate suspension of Drug Enforcement Administration (DEA) Certificate of Registration RA0210409, pursuant to 21 U.S.C. § 824(d), because such registration constitutes an imminent danger to the public health and safety. DEA Certificate of Registration RA0210409 is assigned to Respondent's Orlando Distribution Center. Notice is also given to afford Respondent an opportunity to show cause before the DEA, at DEA Headquarters, 600 Army Navy Drive, Arlington, Virginia, on June 4, 2007 (if Respondent requests such a hearing), as to why DEA should not revoke its registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. § 823(e), because Respondent's continued registration is inconsistent with the public interest, as that term is defined by 21 U.S.C. §§ 823(d) and 824(a)(4). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth below:

1. Respondent has failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1). From January 1, 2006, through January 31, 2007, Respondent distributed over 3.8 million dosage units of combination hydrocodone products to customers that it knew or should have known were diverting the hydrocodone into other than legitimate medical, scientific and industrial channels. Hydrocodone, in the formulation that Respondent distributed, is a schedule III narcotic controlled substance that is addictive and widely abused.

2. Several of Respondent's largest purchasers of hydrocodone in 2005 and 2006 were pharmacies engaged in schemes to dispense controlled substances based on prescriptions that are issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. These pharmacies distributed large amounts of controlled substances based

on orders placed by customers using various Internet websites. Practitioners then "approved" prescriptions for controlled substances and sent them via the Internet or facsimile to the dispensing pharmacies. In many instances, the prescribing and/or dispensing of controlled substances violated state laws.

3. From January 2006 through January 2007, Respondent distributed approximately 1,006,300 dosage units of generic and brand name hydrocodone and hydrocodone combination products to Grand Pharmacy (Grand), of New Port Richey, Florida, under circumstances that clearly indicated that Grand was engaged in the diversion of controlled substances.

4. Respondent also supplied generic and brand name hydrocodone and hydrocodone combination products under similarly suspicious circumstances to Discount Mail Meds, LLC, Medassist RX, LLC, and Avee Pharmacy, Inc., among others. Respondent distributed hydrocodone under the following circumstances that should have alerted Respondent that the pharmacies were diverting hydrocodone:

a. Respondent distributed hydrocodone to each of the named pharmacies, and others, in amounts that far exceeded what an average pharmacy orders to meet the legitimate needs of its customers. Respondent knew that orders of an unusual size were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b).

b. Respondent distributed hydrocodone to each of the named pharmacies, and others, even though the pharmacies ordered small amounts of other drug products relative to the pharmacies' hydrocodone purchases from the Respondent. Respondent knew orders for large amounts of hydrocodone in combination with small amounts of other drug products deviated from the normal pattern of orders placed by pharmacies. Respondent knew that orders that deviate substantially from a normal pattern were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b).

c. Respondent distributed hydrocodone to each of the named pharmacies, and others, even though the pharmacies ordered hydrocodone much more frequently than Respondent's other pharmacy customers. Respondent knew that orders of unusual frequency were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b).

d. Public information regarding several of Respondent's pharmacy customers was readily available to Respondent. Had Respondent attempted to learn about these pharmacies prior to filling the suspicious orders placed by the pharmacies, Respondent would have known that many of the named pharmacies were filling prescriptions that were issued by physicians acting outside the usual course of professional practice in violation of 21 C.F.R. § 1306.04. Specifically, the prescriptions filled by the pharmacies were issued by physicians who did not conduct a medical examination of the customers, but rather wrote prescriptions for controlled substances that were ordered by customers over the Internet.

5. On August 10, 2005, DEA personnel met with Steve Mays, Respondent's Director of Regulatory Affairs, to inform him about the common characteristics of pharmacies that divert large amounts of controlled substances by filling invalid prescriptions obtained by customers using the

Internet. DEA personnel reminded Respondent that, under 21 U.S.C. §§ 823(b)(1) and (e)(1), Respondent was responsible to prevent the diversion of controlled substances. Notwithstanding the information provided to Respondent, after the August 10, 2005 meeting, Respondent sold over 5.2 million dosage units of hydrocodone to pharmacies that bore the characteristics that DEA described in the August 10, 2005 meeting. Respondent continued to sell controlled substances to Grand, Discount Mail Meds, and Medassist even though Respondent knew, or should have known, that these pharmacies were diverting controlled substances into other than legitimate medical, scientific and industrial channels. In January 2007, Respondent sold approximately 287,700 dosage units of hydrocodone to Medassist, 184,200 dosage units to Discount Mail Meds, and 128,000 dosage units to Grand. In February 2007, Respondent sold approximately 196,100 dosage units of hydrocodone to Medassist and 172,100 dosage units to Discount Mail Meds. Respondent continues to sell controlled substances to Discount Mail Meds.

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(b), 823(e) and 824(a)(4), it is my preliminary finding that Respondent has failed to maintain effective controls against diversion and that the continued registration of Respondent would be inconsistent with the public health and safety. Moreover, it is my preliminary conclusion that Respondent's continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety because of the substantial likelihood that Respondent will continue to supply pharmacies that divert large quantities of controlled substances. Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RA0210409 is hereby suspended, effective immediately; such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal and/or to remove for safekeeping all controlled substances that Respondent possesses pursuant to its registration, which I have herein suspended. The said Agents and Investigators are also directed to take into their possession Respondent's DEA Certificate of Registration and any unused order forms.

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension, Respondent may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. See 21 C.F.R. § 1301.43(a). If Respondent fails to file such a request, the hearing set for June 4, 2007, shall be terminated in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Respondent may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Respondent's position on the matters of fact and law involved. See 21 C.F.R. §1301.43(c).

3. Should Respondent decline to file a request for a hearing or, should Respondent request a

hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. See 21 C.F.R. §§ 1301.43(d), 1301.43(e).

Correspondence concerning this matter, including the requests referenced in paragraph 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. See 21 C.F.R. § 1316.

4/19/07

Michele M. Leonhart
Deputy Administrator

cc: Hearing Clerk
Office of Administrative Law Judges

REQUEST FOR HEARING

Any person desiring a hearing with respect to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

Hearing Clerk
Office of the Administrative Law Judges
Drug Enforcement Administration
Washington, D.C. 20537

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

(A) [State with particularity the interest of the person in the proceeding.]

(B) [State with particularity the objections or issues, if any concerning which the person desires to be heard.]

(C) [State briefly the position of the person with regard to the particular objections or issues.]

(D) [Name (either registrant, applicant, or attorney), address (including street address, city, state and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant,
applicant, or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.